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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/459,979	12/14/1999	MARK WILLIAM JAMES FERGUSON	39-196	1874

7590                    04/10/2002

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[REDACTED] EXAMINER

JIANG, DONG

ART UNIT	PAPER NUMBER
1646	12

DATE MAILED: 04/10/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No.	Applicant(s)
	09/459,979	FERGUSON, MARK WILLIAM JAMES
	Examiner  Dong Jiang	Art Unit  1646

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 31 January 2002.
- 2a) This action is FINAL.                    2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.
- 4) Claim(s) 39-45 is/are pending in the application.  
4a) Of the above claim(s) 44 and 45 is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 39-43 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) 39-45 are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) The proposed drawing correction filed on \_\_\_\_\_ is: a) approved b) disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) The oath or declaration is objected to by the Examiner.

#### Priority under 35 U.S.C. §§ 119 and 120

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) All b) Some \* c) None of:  
1. Certified copies of the priority documents have been received.  
2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) The translation of the foreign language provisional application has been received.
- 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

#### Attachment(s)

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                   | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____  |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                          | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>11</u> . | 6) <input type="checkbox"/> Other: _____                                    |

**DETAILED OFFICE ACTION**

Applicant's amendment in paper No. 11, filed on 31 January 2002 is acknowledged and entered. Following the amendment, claims 33-38 are canceled, and the new claims 39-45 are added.

Newly submitted claims 44 and 45 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: the claim limitation of claim 44 states that "IFN- $\gamma$  is administered either immediately prior to wounding or immediately after wounding", indicating the claimed method is for acute wound, which is not presented in the invention as originally claimed (for chronic wound), and is distinct from the chronic wound as the reasons and pathological mechanisms involved in acute wound is different from those in chronic wound, thus non-coextensive searches are required for acute and chronic wounds. With respect to the new claim 45, the claim limitation as originally presented is to administer a *stimulator* of IFN- $\gamma$  (see the independent claim 25, or 33), which is distinct from an inhibitor of IFN- $\gamma$  metabolism. The application of an inhibitor of IFN- $\gamma$  metabolism indicates the presence of IFN- $\gamma$  and/or degradation factors thereof at the wound site, and the involvement of possible distinct pathological mechanism from that requires a stimulator of IFN- $\gamma$ . Therefore, non-coextensive searches are required for applying a stimulator of IFN- $\gamma$  and an inhibitor of IFN- $\gamma$  metabolism.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 44 and 45 withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Currently claims 39-45 are pending, and claims 39-43 are under consideration.

**Withdrawal of Objections and Rejections:**

All objections and rejections of claims 33-38 are moot as the applicant has canceled the claims.

The rejection of claims 33-35, 37 and 38 under 35 U.S.C. 112, first paragraph for lack of enablement made in the last Office Action (paper No. 7, page 3) will not be applied to the newly added claims 39-43, which are directed to the same subject matter as that of the canceled claims 33-35, 37 and 38, in view of applicant's amendments.

**Rejections Over Prior Art:**

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 39-43 rejected under 35 U.S.C. 103(a) as being unpatentable over Mustoe et al. (J. Clin. Invest., 1991, 87(2):694-703), and Badgett et al. (J. Lipid mediators Cell signaling, Jan. 1996, 13(1): 89-97).

Pierce, cited by applicants, discloses that PDGF is one of polypeptide growth factors that have significant activity in tissue repair processes, and is released by platelets, activated macrophages, and cells required for normal wound repair, and that PDGF is a potent chemoattractant for wound cells and is able to activate critical activities for wound healing within the cells (the first paragraph of the Introduction). The reference does not teach the effect of IFN- $\gamma$  on wound healing.

Badgett teaches that PDGF is a potent mediator of fibroblast proliferation and chemotaxis (the abstract, lines 1-2), that IFN- $\gamma$  is known to prime macrophages for increased PDGF production, and that there is a clear concentration-dependent priming effect of IFN- $\gamma$  on the secretion of macrophage-derived PDGF, and at 10000 U/ml, IFN- $\gamma$  causes more than 5-fold increase in PDGF release (page 92, the second paragraph, and Figure 2), however, lower concentrations of IFN- $\gamma$  (under 1000 IU) block PDGF-induced fibroblast proliferation (page 90, the last paragraph of the introduction, Figure 3).

It would have been obvious to the person of ordinary skill in the art at the time the invention was made to use higher doses of IFN- $\gamma$  (as in claim 41) to treat wounds because of

the teachings by Badgett that IFN- $\gamma$  stimulates PDGF production in a dose dependent fashion, and the lower dose would block PDGF-induced fibroblast proliferation, and the teachings by Pierce that PDGF has an important role in tissue repair processes. The person of ordinary skill in the art would have been motivated to do so for the treatment of wounds, and reasonably would have expected success because Pierce has established the specific and unique in vivo function of PDGF in promoting reepithelialization of wounds and stimulating significant new granulation tissue in the animal model of wound, and Badgett has demonstrated the positive priming effect of IFN- $\gamma$  on the secretion of PDGF.

**Conclusion:**

No claim is allowed.

Art Unit: 1646

**Advisory Information:**

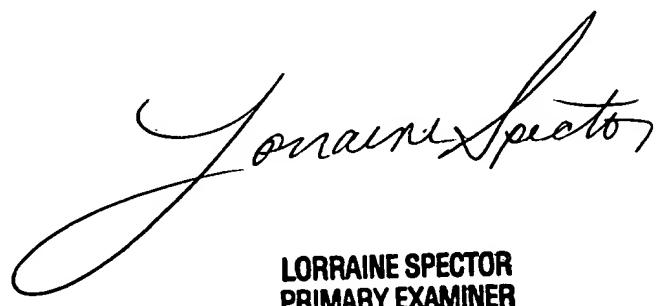
Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication should be directed to Dong Jiang whose telephone number is 703-305-1345. The examiner can normally be reached on Monday - Friday from 9:00 AM to 6:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler, can be reached on (703) 308-6564. The fax phone number for the organization where this application or proceeding is assigned is 703-308-0294.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.



LORRAINE SPECTOR  
PRIMARY EXAMINER

DJ  
4/1/02